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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/577,601

Applicant(s)

LOOSMORE ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, drawn to an expression vector comprising a nucleic acid sequence encoding a non-proteolytic analog of Hin47, or a Hin47 analog and at least one other protein, classified in class 435, subclass 320.1;
  - II. Claims 17-36, drawn to a method of protein expression of a non-proteolytic analog of Hin47, or of a Hin47 analog and at least one other protein, classified in class 435, subclass 69.3;
  - III. Claims 37, 38, and 42, drawn to an expression vector comprising a nucleic acid sequence encoding hmwB, or encoding hmwB and at least one other protein, classified in class 435, subclass 320.1;
  - IV. Claims 37, 38, 39, and 43, drawn to an expression vector comprising a nucleic acid sequence encoding hmwC, or encoding hmwC and at least one other protein, classified in class 435, subclass 320.1; or
  - V. Claims 40 and 41, drawn to an expression vector comprising a nucleic acid sequence encoding hmwBC, or encoding hmwBC and at least one other protein, classified in class 435, subclass 320.1.
2. This application contains claims directed to the following patentably distinct species of the claimed invention:

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- (A) an expression vector comprising the nucleic acid sequence as per one of (the elected) the expression vectors, or the method of expressing proteins, in Groups I - II and a nucleic acid sequence encoding the Hia protein of *Haemophilus influenzae*;
- (B) an expression vector comprising the nucleic acid sequence as per one of (the elected) the expression vectors, or the method of expressing proteins, in Groups I - II and a nucleic acid sequence encoding the Hsf protein of *Haemophilus influenzae*; or
- (C) an expression vector comprising the nucleic acid sequence as per one of (the elected) the expression vectors, or as used in the method of expressing proteins, in Groups I - II and a nucleic acid sequence encoding the PsaA protein of *Streptococcus pneumoniae*.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8, 17-20, and 26-28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**The inventions of Groups I-V are distinct, each from the others, for the following reasons:**

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, both of the above may be shown. The process of use as claimed may be used with a materially different product from the invention claimed in Group I. Group I is to an expression vector comprising two proteins. The method of Group two may be used with that expression vector, but may also be used by transforming a cell with two separate nucleotide strands.

The expression vector may also be used for a purpose other than for protein expression. It may also be used for hybridizing a cell. Thus, because the process may be used with other products (as described above), and because the product may be used in other processes, the inventions are distinct.

4. Inventions I and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different

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inventions are expression vectors that encode for different proteins- Hin47, or HmwB, HmwC, or HmwBC. As these expression vectors are not disclosed as usable together, and because they each code for a different protein (thus perform different functions and have different effects), the vectors are distinct.

5. Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, inventions III and IV each have a separate utility since each can independently be used in an expression vector according to the claimed inventions. Because both inventions II and IV are independently usable, as well as usable in combination, they are distinct inventions.

6. Invention V, and inventions III and IV are related as combination and subcombinations. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombinations as claimed because patentability of the combination may be established by either one of the subcombinations, or by the combination the two. Both subcombinations have a separate utility as an expression vector independently of each other and of the combination. Therefore, the combination and the subcombinations are distinct.

7.

### *Claim Objections*

8. Claim 26 is objected to because of the following informalities:

- Claim 26 should read: "said first nucleic acid encodes the *natural* form of the non-proteolytic analog," rather than "the nature form." Appropriate correction is required.

*Examiner's notes*

9. Claims 24, 32, 33, 35, and 36 recite the limitation "the method of claim 21 wherein said vector is a plasmid vector." There is insufficient antecedent basis for this limitation in the claim because the line of claims nowhere mentions that there is one vector involved. Claim 17, the independent claim from which these claims stem, claims a method of expressing at least one protein comprising introducing a first nucleic acid molecule encoding a Hin47 analog, and a second nucleic acid molecule encoding a protein other than Hin47, into a cell to transform it. Nowhere in this claim, or in the claims between it and the recited dependant claims is a vector introduced. Further, although a vector could be considered to be any DNA fragment, in the relevant claims, there are two, not one, potential vectors- neither of which is identified as a vector exclusively of the other.

10. Claims 38, 41, and 42 all claim specific plasmids identified by number, and by reference to figures included in the specification. Claims 38 and 42 claim expression vectors identified by the phrase "plasmid IN-137-1-16 shown in Figure 18a." However, figure 18A does not identify a plasmid IN-137-1-16. Likewise, claim 41 claims the expression vector with the characteristics of "plasmid IN-52-1-13 as shown in Figure 17A." Plasmid IN-52-1-13 is not identified in figure 17A.

### Conclusion

11. Because these inventions are distinct for the reasons given above and the search required for each of the Groups requires searching not required for the others, restriction for examination purposes as indicated is proper.

12. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product,

#### Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an**



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allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
April 8, 2002

  
JAMES HOUSEL 4/8/02  
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